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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,578	10/26/2001	Jeffrey S. Kiel	PEDI-04	4696

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EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/047,578	KIEL ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 31-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 31-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/06/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of applicants' filing of an amendment filed April 06, 2007. . By the amendment, claims 1 and 31 have been amended and claim 53 has been cancelled.

2. Claims 1-21 and 31-48 are currently pending for prosecution on the merits.

3. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

4. Applicant's amendment requiring "said composition that consists of the tannate salts of pyrilamine and phenylephrine" necessitates a new ground of rejection in this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-21 and 31-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 31 recite the limitation "said composition that consists essentially of". There is insufficient antecedent basis for this limitation in the claim.

It is noted to applicant that this rejection could be obviated by amending "A composition comprising: a plurality of active pharmaceutical ingredients consisting essentially of phenylephrine and pyrilamine" to "A composition consisting essentially of phenylephrine and pyrilamine".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-21, 31-48 and 53 is rejected under 35 USC 103(a) as being unpatentable over Gordiziel (US 6287597) in view of Chopdekar et al. (US 5599846).

Gordiziel discloses a composition consisting essentially of phenylephrine tannate and pyrilamine tannate and the unspecified components such as benzoic acid, coloring, natural and artificial flavors, glycerin, kaolin, magnesium aluminum silicate, methyl paraben, pectin, purified water, saccharin, sodium hydroxide and sucrose or sorbitol, wherein said composition is prepared in a conventional manner; and wherein said composition is prepared in various dosage forms including suspension such that each 5ml (one teaspoon) contains 30mg of pyrilamine tannate and 5mg of phenylephrine tannate (column 2, lines 51-64 and Examples 1-2). Gordiziel discloses that beside the conventional isopropanol route, antihistamines in the form of their

tannate salts can be prepared alternatively in the water route (column 1, line 60 thru column 2, line 6).

Chopdekar discloses an antihistamine tannates (e.g., phenylephrine, pyrilamine, etc...) prepared by water route. Chopdekar teaches or suggests the advantage of preparing antihistamine tannates in water route compared to the conventional isopropanol route, wherein the water route yields about 90-97% of the tannate salts products and about 90-98% of the product purity compared to only about 70% of the yields and about 85-90% wt % of the purity in the isopropanol route.

As indicated in preceding statement, both the referenced composition (Gordiziel) and the claimed composition (final composition prepared by the claimed steps) are directed to the same composition. However, the teaching of Gordiziel'597 differs from the claimed invention in (i) the specific step of making said composition by the water route, namely step of conversion of the active pharmaceutical ingredients into tannate salts prepared by reacting phenylephrine and pyrilamine in the form of free base with tannic acid in the presence of water and mixing with the known secondary agents or dispersing agents to derive at the claimed homogenous suspension, homogenous granulation or homogenous composition (being in an amount including a plurality of dosage units, the homogenous suspension, granulation or composition being homogenous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units"), without isolation or purification step; (ii) the specific amounts (or ratios) of active and/or inactive ingredients in a composition; and (iii) the specific pH of the said composition. To incorporate such teaching into the teaching of Gordiziel, would have been

obvious in view of Chopdekar who teaches or suggests the advantage of preparing antihistamine tannate in water route.

One having ordinary skill in the art would have been motivated to prepare the claimed composition by the water route such that the yield and the purity of antihistamine (pyrilamine and phenylephirne) tannates would be greatly increased. Although the prior art references in combination do not specifically disclose the claimed order (or step) of preparing said composition, such determination of order of performing step is prima facie obvious in the absence of new or unexpected results.

The patentability of the product is not dependent upon the manner in which is produced unless the process changes the product. In this situation, both products in the prior art and the instant invention are drawn to the same composition.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

In addition, optimization of amounts (or ratios) of known active and inactive ingredients in a composition or determination of optimum pH is well considered within the skill of the artisan, absent evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-21, 31-48 and 53 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-21, 31-48 and 53 of copending Application No.10/645977. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claimed invention overlaps to each other.

The copending application is directed to a composition comprising component A (phenyephrine), component B (pyrilamine) and component C (dextromethorphan) whereas the instant invention is directed to a composition consisting essentially of component A (phenylephrine) and component B (pyrilamine). The selection of the components A and B from composition comprising the components A, B and C to make the composition consisting essentially of the components A and B is considered obvious task for the skilled artisan, in absence evidence to the contrary or showing that the introduction of steps or components would materially change the invention.

Until the appropriate Terminal Disclaimer is filed by the applicant and approved in our PTO record, the examiner maintains above obviousness-type double patenting rejection for the reasons of record.

Response to Arguments

8. Applicants' arguments filed April 06, 2007 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the similar position to the previous arguments considered (February 23, 2004, July 22, 2004, November 03, 2005 and July 24, 2006) that neither of the references cited by the Examiner, alone or in combination, disclose or suggest a composition that will exhibit the same level of reduced variability in active drug content and increased certainty that the active pharmaceutical ingredients are delivered within a therapeutic range as claimed in the present application. Applicant asserts that the process of the independent claims renders a product different from that produced by Gordiziel alone or in combination with Chopdekar.

Applicant's argument is not found persuasive. Unlike the applicant's argument, the patentability of the product is not dependent upon the manner in which is produced unless the process changes the product. In this situation, both products in the prior art and the instant invention are drawn to the same composition, a composition consisting essentially of phenylephtrine and pyrilamine in the form of their tannate salts in overlapping dosage amounts. Regardless of the alleged "without isolation or purification" process or the uniformity of the composition or homogenous suspension, granulation or composition from one dosage unit to the next, the instantly claimed composition is obvious over the cited references in combination

(Gordiziel and Chopdekar), especially in view of about 90-98% of the product purity prepared by the prior art method (Chopdekar).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. No Claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
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